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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/665,363	09/19/2000	Y. Tom Tang	789CIP2C	5054

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Leslie A Mooi
Hyseq Inc
670 Almanor Avenue
Sunnyvale, CA 94085

EXAMINER
ARTHUR, LISA BENNETT

ART UNIT	PAPER NUMBER
1655	6

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/665,363	Applicant(s) TANG ET AL.	
	Examiner Lisa B. Arthur	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups I-35. Claims 1-9,19 drawn to a polynucleotide selected from any one of SEQ ID Nos 1-35, a vector a host cell and a method of using the polynucleotide to make the encoded polypeptide, classified in class 536, subclass 23.5 and class 435, subclasses 320.1, 325 and 69.1. For instance, if Group 1 is elected, a polynucleotide of SEQ ID NO 1 will be examined and if Group 35 is elected, a polynucleotide of SEQ ID NO 35 will be examined.

Groups 36-70. Claims 10-11, and 20, drawn to a polypeptide encoded by any one of the sequences of SEQ ID Nos 1-35, classified in class 530, subclass 350. For instance, if Group 36 is elected, a polypeptide encoded by SEQ ID NO 1 will be examined and if Group 0 is elected, a polypeptide encoded by of SEQ ID NO 35 will be examined.

Groups 71-105. Claim 12, drawn to an antibody directed against any one of SEQ ID Nos 1-35, classified in class 350, subclass 387.1.

Groups 106-140. Claims 13-15, drawn to a method for detecting any one of the polynucleotides of SEQ ID Nos 1-35, classified in class 435, subclass 6 and 91.2.

Groups 141-175. Claims 16-18, drawn to a method for detecting a polypeptide encoded by any one of the sequences of SEQ ID Nos 1-35 or a compound which binds to this polypeptide, classified in class 435, subclass 7.1.

Groups 176-210. Claim 21, drawn to a polypeptide array comprising a polypeptide encoded by any one of the sequences of SEQ ID Nos 1-35 , classified in class 530, subclass 350.

Groups 211-245. Claims 22-26, drawn to a polynucleotide array, classified in class 536, subclass 24.3.

Groups 246-280. Claim 27, drawn to a method of treatment comprising administration of any one of the polypeptides encoded by SEQ ID Nos 1-35, classified in class 514, subclass 8.

Groups 281-315. Claim 28, drawn to a method of treatment comprising administration of an antibody that specifically binds to any one of the polypeptides encoded by SEQ ID Nos 1-35, classified in class 424, subclass 130.1.

The inventions are distinct, each from the other because:

First, Applicant should note that all of the claims are improper Markush claims because each of the recited SEQ ID Nos represents a distinct invention. Each of the sequences of SEQ ID Nos 1-35 has a different structure, i.e. nucleotide sequence, and is presumed therefore to have different functions. As a result applicant is required to elect a single sequence to be examined in the context of one of the following distinct inventions.

Each of the polynucleotides of Groups 1-35 is patentably distinct from each of the polypeptides of Groups 36-70 because they have different structures and different

functions. The polynucleotides are composed of nucleotides linked by phosphodiester bonds and arranged in anti parallel alignment in a double helical configuration. The polynucleotides can function as probes and primers in hybridization based assays. In contrast, the polypeptides are composed of amino acids linked by peptide bonds and arranged in a combination of complex secondary and tertiary structures such as alpha helices, beta pleated sheets, hydrophobic and hydrophilic domains. The polypeptides can function in the affinity purification of binding antibodies or as therapeutic agents. Therefore, the polynucleotides of Groups 1-35 and the polypeptides of Groups 36-70 are novel and unobvious over one another.

Inventions 1-35 and 36-70 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptides can be mase in a materially different process such as by chromatographic methods.

Groups 36-70 and Groups 71-105 are patentably distinct inventions because the polypeptides of Groups 36-70 are structurally anf functionally different from the antibodies of Groups 71-105. , While the polypeptides and he antibodies are both composed of amino acids linked by peptide bonds, they have completely different tertiary structures and distinct functions. Specifically the antibodies contain an epitopic region which specifically binds to a specific portion of a polypeptide to mark a specific peptide as foreign to an animal's immune system. The polypeptides of the invention

appear to function in a number of different cellular processes, i.e. sich as enzymes and structural proteins, according to Table 2. Therefore, each of these products is novel and unobvious over one another.

Inventions 1-35 and 106-140 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotides can be used to produce the encoded polypeptides or as a therapeutic agent.

Inventions 36-70 and 141-175 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides can be used in a materially different method such as the affinity purification of a specific binding protein or in a therapeutic method.

Inventions 71-105 and 141-175 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies

can be used in a materially different process such as for the affinity purification of the polypeptide or in a therapeutic method.

Inventions 36-70 and inventions 176-210 are patentably distinct because they are different in structure and function. The polypeptide of groups 36-70 is a single polypeptide having a specific amino acid sequence and which can be used to affinity purify specific binding compounds. The polypeptide array of groups 176-210 is composed of a plurality of polypeptides immobilized on a solid support at specific and discrete locations and is used to screen for binding compounds and for substrates, wherein only one of the polypeptides is encoded by one of SEQ ID Nos1 –35. Therefore, these inventions are novel and unobvious over one another.

Inventions 1-35 and inventions 211-245 are patentably distinct because they are different in structure and function. The polynucleotide of inventions 1-35 is a single polynucleotide encoding a specific polypeptide that has a particular cellular function. The polynucleotide array of groups 211-245 is composed of a plurality of polypeptides immobilized on a solid support at specific and discrete locations and is used to screen which are complementary to any of the sequences of the array, wherein only one of the polynucleotides is SEQ ID Nos1 –35. Therefore, these inventions are novel and unobvious over one another.

Inventions 36-70 and 246-280 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used in a materially different method such as the affinity purification of a specific binding compound.

Inventions 71-105 and 281-315 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used in a materially different method such as the affinity purification of a polypeptide to which it specifically binds.

The methods invention 141-175 and 246-280 and 281-315 are each patentably distinct from one another because they each have different objectives, use different reagents and have different method steps. The method of groups 141-175 uses an antibody to detect the presence of a protein to which it specifically binds by forming an detecting a complex. The method of using the antibody for treatment requires not only the specific binding of the antibody to a protein but also the removal or modification of that protein to illicit a positive effect in an organism. The treatment method using the protein is different from the treatment method using the antibody because the stability, dosage, and effect of administering a protein is completely different that that of administration of the antibody. Therefore, these methods are each novel and unobvious over one another.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa B. Arthur whose telephone number is 308-3988. The examiner can normally be reached on Monday-Wednesday from 7:00 am to 2:30 pm. The examiner can also be reached on alternate .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for the organization where this application or proceeding is assigned is 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196.

LISA B. ARTHUR
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

December 17, 2001